

## **II. REMARKS**

### **A. Status of the Claims**

Claims 1-19 were pending in the case at the time of the Office Action. Claim 9 has been amended in the Amendment set forth herein. In particular, claim 9 has been amended to replace “about 0.26 mg/m<sup>2</sup>/day to about 1.04 mg/m<sup>2</sup>/day” with “about 6.7 µg/kg/day to about 26.6 µg/kg/day.” An example of support for “about 6.7 µg/kg/day to about 26.6 µg/kg/day” can be found on page 16, lines 10-13 of the specification. Claims 1 and 12-17 have been previously canceled without prejudice or disclaimer. No new claims have been added. Therefore, claims 2-11 and 18-19 are currently under consideration.

### **B. Teleconference with Examiner and Interview Summary**

On May 23, 2007, Examiner Aradhana Sasan telephoned Applicants’ representative, Monica De La Paz, to discuss the response to the Office Action dated January 31, 2007. Examiner Sasan indicated that she would be willing to issue a Notice of Allowance if Applicants filed a terminal disclaimer over U.S. Patent 6,090,407. Applicants’ representative stated to the Examiner that the matter would be discussed with the client and the Examiner would be contacted once a decision had been reached.

On May 29, 2007, Applicants’ representative, Monica De La Paz, telephoned the Examiner to indicate that Applicants would be willing to file a terminal disclaimer over U.S. Patent 6,090,407. Applicants’ representative reminded the Examiner that the present application is a continuation-in-part of U.S.S.N. 09/969,674, which in turn claims priority (through two continuing applications) back to U.S. Patent 6,090,407. Applicants’ representative noted that the present specification recites a concentration range of “about 0.26 mg/m<sup>2</sup>/day to about 1.04 mg/m<sup>2</sup>/day or about 6.7 µg/kg/day to about 26.6 µg/kg/day.” Specification, page 16, lines 10-13. Applicants’ representative also pointed out that U.S. Patent 6,090,407 recites a concentration

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range of “about 8  $\mu\text{g/kg}$  of patient weight/day to about 100  $\mu\text{g/kg}$  of patient weight/day for 9-NC.” col. 6, lines 51-54 of U.S. Patent 6,090,407. In view of the recitation of a concentration range in units of  $\mu\text{g/kg/day}$  rather than  $\text{mg/m}^2/\text{day}$  in U.S. Patent 6,090,407, Applicants requested guidance from the Examiner as to whether it would be preferred for the presently pending claims to recite a concentration range in units of  $\mu\text{g/kg/day}$  rather than  $\text{mg/m}^2/\text{day}$ , specifically “about 6.7  $\mu\text{g/kg/day}$  to about 26.6  $\mu\text{g/kg/day}$ ” rather than “about 0.26  $\text{mg/m}^2/\text{day}$  to about 1.04  $\text{mg/m}^2/\text{day}$ .” The Examiner indicated that she would discuss the matter with her supervisor. The Examiner telephoned Applicants’ representative later in the day on May 29, 2007, and informed Applicants’ representative that amendment to the claims to recite units of  $\mu\text{g/kg/day}$  as discussed above with filing of a terminal disclaimer as discussed above would be acceptable and would result in a Notice of Allowance. Applicants herein amend independent claim 9 (and claims that depend therefrom) to recite a concentration range of “about 6.7  $\mu\text{g/kg/day}$  to about 26.6  $\mu\text{g/kg/day}$ ” and to submit a terminal disclaimer over U.S. Patent 6,090,407.

### **C. The Nonstatutory Obviousness-Type Double Patenting Rejection Is Overcome**

Claims 1-19 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent 6,090,407 (“the ‘407 patent”) in view of Burke (U.S. Patent 5,736,156) and Priel *et al.* (U.S. 5,422,344; “Priel”). The Examiner asserts that although the conflicting claims are not identical, they are not patentably distinct. Applicants respectfully traverse.

Without conceding that claims 1-19 are not patentably distinct over claims 1-4 of U.S. Patent 6,090,407, Applicants will overcome this issue by filing a terminal disclaimer over U.S. Patent 6,090,407. A terminal disclaimer is concurrently filed herewith.

**D. Conclusion**

In view of the foregoing, it is respectfully submitted that each of the pending claims is in condition for allowance, and a Notice of Allowance is earnestly solicited. The Examiner is invited to contact the undersigned attorney at (512) 536-5639 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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